Proposed Issues and Background for the National Pollution Prevention and Toxics Advisory Committee (NPPTAC)

Prepared by the
Office of Pollution Prevention and Toxics (OPPT)

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Introduction

In 1997, the Environmental Defense Fund (now Environmental Defense or ED) published *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States.*[1] The ED report stated that approximately 75% of the high production volume (HPV) chemicals in commerce do not have publicly available basic hazard information associated with them. ED analyzed searches of public databases for one hundred of the approximately 3,000 HPV chemicals.

An analysis by the U.S. Environmental Protection Agency (EPA) in 1998[2] confirmed that very little basic toxicity data was publicly available on most of the HPV chemicals listed on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory ("Inventory"). EPA found that, of the 2,800 non-polymeric organic substances produced or imported in amounts equal to or greater than one million pounds per year based on 1990 Inventory Update Rule (IUR) reporting, only 7% have a full data set of publicly available, internationally recognized basic health and environmental fate/effects screening test data, while 43% have no publicly available basic hazard data. For the remaining chemicals, limited amounts of the data are available. A third study performed by industry arrived at a similar conclusion.[3]

This lack of available hazard data limits EPA's and others' ability to determine whether these HPV chemicals pose potential risks to human health or the environment. In addition, the lack of publicly available data restricts the public's right-to-know about the hazards of chemicals that may be found in their environment, their homes, their workplaces, and the products that they buy. Thus, on April 21, 1998, a national initiative, known as "Chemical Right-To-Know (ChemRTK)," was announced in order to provide citizens with information about the highest volume chemicals in commerce. The ChemRTK Initiative is an effort to fill this knowledge gap by rapidly collecting and making basic information about chemicals publicly available. The ChemRTK Initiative includes the HPV Challenge Program and the Voluntary Children's Chemical Evaluation Program (VCCEP).

This background document will focus on the HPV Challenge Program.

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[1] Environmental Defense 1997. *Toxic Ignorance*. New York, New York, (Summer 1997). Copies can be obtained by accessing ED's web site (non-EPA site) at http://www.environmentaldefense.org/documents/243_toxicignorance.pdf or by calling 1–800–684–3322.

[2] EPA, OPPT. *Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals?* (April 1998) (http://www.epa.gov/opptintr/chemtest/hazchem.htm).

[3] ACC 1998. *Public Availability of SIDS Related Testing Data for U.S. High Production Volume Chemicals* (June 12, 1998). Copies of ACC's report can be obtained by writing to ACC at 1300 Wilson Blvd., Arlington, VA 22209 or by calling ACC at (703) 741–5226. (Note: The Chemical Manufacturers Association (CMA) is now the American Chemistry Council (ACC)).

The Challenge and Industry's Response

The framework for the HPV Challenge Program was developed by Environmental Defense and the American Chemistry Council. U.S. producers and importers of HPV chemicals participate voluntarily in the HPV Challenge Program by collecting and submitting to EPA basic hazard data on the HPV chemicals they produce or import.[4] Industry has responded to the challenge by sponsoring over 2,100 HPV chemicals in the Challenge Program. As of October 3, 2003, 333 U.S. chemical companies and 97 consortia (companies working together to meet the Challenge) volunteered to provide EPA and the public with data on 2,167 HPV chemicals over a five-year period. Since the spring of 2000, industry has been submitting existing data and/or providing test plans for generating and submitting data. Full data sets for each sponsored chemical or category of chemicals take approximately two years to complete, so chemicals that were started in the first full year of the program are just now completing the process.

EPA has issued a proposed test rule under TSCA §4 to obtain hazard information on a portion of the HPV chemicals that have not been sponsored. The first such rulemaking was proposed in December 2000, covering 37 HPV chemicals. The final rule is planned for promulgation in 2003. Additional HPV test rules addressing other unsponsored chemicals are also under consideration.

What Are Basic Hazard Data?

The information relevant to understanding the basic health and environmental hazards of HPV chemicals is derived from a battery of tests agreed upon by the international community as appropriate for hazard screening purposes. The battery of endpoints has been developed and adopted by the Organization for Economic Cooperation and Development (OECD) and is known as the OECD's Screening Information Data Set (SIDS). These data include: physicochemical properties (melting point, boiling point, vapor pressure, water solubility, and octanol/water partition coefficient); environmental fate (biodegradation, hydrolysis, and estimates of distribution/transport and photodegradation); ecotoxicity (acute toxicity to aquatic vertebrates, invertebrates, and plants); and studies in laboratory animals to assess human health effects (acute and repeat-dose toxicity, effects on the gene and chromosome, and effects on reproduction and the developing organism).[5]

How the HPV Program Works: The Process

One of the key components of the HPV Program is making the hazard data described above publicly available. Once a company or consortium makes a commitment to "sponsor" a chemical or group of chemicals (categories), then the company is agreeing to follow the Program's procedures (additional information may be found at http://www.epa.gov/chemrtk/volchall.htm).

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[4] Federal Register. *Data Collection and Development on High Production Volume (HPV) Chemicals*. 65 FR 81686, December 26, 2000.

[5] OECD Secretariat, April, 2003. *Manual for the Investigation of HPV Chemicals*. Available at: http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html.

An HPV Challenge Submission consists of a cover letter, a Test Plan, and Robust Summaries. The *cover letter* generally identifies the company(ies), chemical(s) and usually whether any new testing is being proposed. The *Test Plan* can be a table or narrative (or both) that describes whether data exist for a given endpoint, an evaluation of the data adequacy, an opinion that no new testing is necessary. Where no data exist, or the existing data are considered inadequate, the sponsor proposes to conduct a test(s) for that endpoint. The *Robust Summaries* are summaries generated for each individual study/experiment for each SIDS endpoint.[6] They are designed to provide information to a technical audience in sufficient detail so it would not be necessary to retrieve or look at the original study report.

Once a submission is received by EPA, it is posted on EPA's website noted above for a 120-day comment period. This allows interested parties, EPA, and the general public an opportunity to comment on a test plan or perhaps bring forward information and data unknown to the sponsor. All comments are publicly available and posted on the website. EPA strongly encourages companies which make commitments under the HPV Challenge Program to sponsor a chemical or chemicals not to make Confidential Business Information (CBI) claims on the chemical-company linkage.

Once the comment period is over, sponsors may respond to comments, revise original submissions, and begin any new testing. Once new testing is complete, new information (in the form of Robust Summaries) is submitted to EPA for posting on the website in order to make the submission complete.

Over 85% of the chemicals currently on the HPV Program website are part of a category. This means that the sponsor has made an argument that a group of chemicals can be considered together in addressing the SIDS endpoints. In other words, the sponsor argues that existing data (or proposed testing) on some members of a category of chemicals may be applied to other, untested members.[7] Unlike single chemical submissions, completion of a category submission (once proposed testing is done) includes a *Category Analysis Document* to determine whether the original category proposal was valid.

General Overview of Areas for Which EPA is Requesting NPPTAC Advice

The expected influx of a large amount of hazard information on HPV chemicals will pose many challenges for EPA and others interested in using the data for a variety of purposes. EPA is requesting advice and recommendations on the key elements of an overall approach to using the HPV data, including the most important actions to be taken as completed HPV data are received. EPA is also requesting advice on how best to share the summarized data and other information

[6] EPA has developed numerous guidance documents for the Challenge Program. For example, guidance documents for developing robust summaries and evaluating data adequacy exist for each of the SIDS endpoints (http://www.epa.gov/chemrtk/guidocs.htm).

[7] EPA, OPPT. *Development of Chemical Categories in the HPV Challenge Program* (Draft guidance document dated August 25, 1999 and available at http://www.epa.gov/chemrtk/guidocs.htm).

obtained on HPV chemicals with the public, other Federal agencies, and any other interested parties. EPA requests NPPTAC advice on the following priority areas:

- Using the HPV Hazard Data to Prioritize Chemicals for Further Action
- Obtaining Additional Data Where Needed
- Making the HPV Data More Useable to Stakeholders
- Communication of HPV Data Evaluation Results
- Evaluation of the Category Approach in the HPV Challenge Program
- Addressing HPV Chemicals Not Part of the Challenge Program.

Specific questions are asked for each of these areas below.

Question 1a: Prioritizing the HPV Hazard Data for Further Action

Question 1a. What would be the appropriate factors/criteria to use to prioritize the HPV chemicals for further action?

The HPV Challenge Program will provide hazard data that can be used in initial screening to prioritize the HPV chemicals for further action, data collection, or analysis for risk assessment or risk management purposes. The screening process will determine which HPV chemicals warrant further assessment, and assign a screening outcome (e.g., classification into priority groups and actions associated with each priority group).

EPA is asking for advice on the key elements that should be considered in the development, piloting, and implementation of a screening process and methodology, as well as characteristics of tools or models that could be used as part of an initial screening to enable EPA to set priorities.

Question 1b: Obtaining Additional Data Where Needed

Question 1b. When a chemical is identified as a priority how can relevant exposure and use data (and additional hazard data) be best obtained and made available to government, industry, non-governmental organizations and others to adequately inform risk assessment and risk management decisions for HPV chemicals?

For HPV chemicals identified as chemicals of concern based on the hazard data provided under the HPV Challenge Program, it is likely that additional data will be needed in order to adequately assess the potential risks posed by these chemicals. This additional data could be additional hazard, exposure and/or use data. In some cases, the HPV submission may already have some limited exposure information.

The submitted HPV hazard data may suggest the need for additional information to either clarify or address a potential issue for future risk assessment and/or risk management actions. For example, results of a repeated-dose toxicity test may identify some neurotoxicity effects that

may need to be assessed in a more specific, focused study designed to observe and assess such effects.

Alternatively, the HPV hazard data may also help identify exposure scenarios of most concern; for example, hazard data may indicate a special concern for a given pathway of exposure such as inhalation or dermal exposure. In many cases the needed additional data will be use and exposure information and could include either known or estimated values for: environmental releases and worker exposure during manufacture and disposal processes; bioaccumulation or other mechanisms or pathways that could lead to dietary exposures; presence in consumer products and the likelihood of release and exposure from those products; and the likelihood of release and exposure from final disposal of the chemical (or products containing the chemical) in landfills or incinerators.

EPA has several regulatory tools to obtain needed data.[8] Under TSCA §4, EPA can require the development of data via rulemaking or through an Enforceable Consent Agreement (ECA), or receive reporting by industry via TSCA §8 (i.e., inventory information through §8(a) and substantial risk information through §8(e)).

In order to issue a test rule under TSCA §4, EPA must make certain statutory findings about the substance involved.[9] Rulemaking under TSCA §4 has generally been both lengthy and resource-intensive. As a result, data have been generated under TSCA §4 test rules on only approximately 140 chemicals since the 1970s. An ECA is a publicly negotiated agreement between EPA and interested parties that requires the generation and submission of data to EPA. ECAs are usually less resource-intensive than test rules and can be a much quicker way to obtain data. Since October 1984, EPA has issued a number of ECAs covering approximately 60 chemicals.

The rulemaking authority under TSCA §8 provides EPA with a mechanism to obtain certain exposure data from manufacturers and processors of HPV chemicals. As a result of recent Inventory Update Rule Amendments (IURA) (68 FR Number 4, January 7, 2003, pp. 848-906), beginning with the 2006 reporting year, initial screening level exposure-related data about uses, number of processing and use sites, and workers exposed to HPV chemicals will be reported to EPA/OPPT. A previous voluntary effort called the Use and Exposure Information Project (UEIP) demonstrated that useful screening level exposure information is available from industry and can be used to prepare screening level exposure assessments. The UEIP was a cooperative effort begun in the fall of 1992 between government and industry in recognition of the difficulties encountered in obtaining accurate and up-to-date exposure information on HPV chemicals. Data

[8] Industry or other submitting companies may claim certain information as Confidential Business Information (CBI) under TSCA §14(a). The provision prohibits EPA from disclosing such claimed information to the public, except in certain limited circumstances.

[9] The statutory findings include that there are insufficient data available to determine the effects of the substance on health and/or the environment; and testing is necessary to provide such data; and the substance may present an unreasonable risk of injury to health or the environment," (known as the "risk-based finding"); and/or may be produced at substantial quantities and is reasonably expected to enter the environment in substantial quantities; or may result in significant or substantial human exposure (known as the "exposure-based finding").

collected by EPA under the UEIP were similar to those now being required under IURA. In contrast to the IURA, however, the UEIP only provided onetime reporting of information by a subset of the manufacturers of a small number of selected HPV chemicals (68 FR Number 4, January 7, 2003, p. 853)

One recent example of how EPA has entered into discussion with industry and others on the collection of additional data short of regulatory action is the work being done associated with PFOA (perfluorooctanoic acid and its salts). PFOA is a synthetic chemical used as an essential processing aid in the manufacture of fluoropolymers in many industry segments including automotive, building/construction, electrical and electronics, and carpet and textile industries (e.g., non-stick surfaces on cookware and protective finishes on carpets and clothing). Industry has collected initial human biomonitoring data that indicates potential exposure of the U.S. general population to PFOA at very low levels. EPA has identified areas where additional information could be very helpful in allowing the Agency to develop a more accurate assessment of the potential risks posed by PFOA, and is requesting additional data and public comment on its preliminary scientific findings.

EPA is interested in the advice of the NPPTAC on the best ways to obtain additional hazard data and use and exposure information on those HPV chemicals identified as a priority.

Question 1c: Promoting Use of the HPV Data by Making the Data Accessible, Available, and Useable to Stakeholders

Question 1c. What tools, models or other infrastructure should EPA provide to promote the use of the HPV test summary data by regions and States/Tribes, industry and other technical audiences?

The HPV Challenge data are submitted in the form of Robust Summaries that are included on EPA's website. The current format of these summaries is primarily viewed as useful to technical audiences. EPA is interested in input from the NPPTAC on what other formats would be most useful to technical audiences including the regions, States, and industry. EPA is in the process of defining core requirements for a searchable database that, once completed, will provide the infrastructure needed to house HPV data and make it more accessible and available in ways that are more useful to diverse technical audiences.

In addition to the packaging and display of the technical information (the database), EPA wishes to facilitate the use of this information. For example, one use is the ability of technical audiences to conduct independent analyses of the HPV data to understand hazard and potential risks of interest to them and possibly others. Current EPA tools and models that have been developed by OPPT over the years to evaluate both new and existing chemicals might be of value in this regard .

EPA is seeking the advice of the NPPTAC on both the HPV database and the appropriate "tool box" of models that would be useful to technical audiences interested in using the HPV data.

Question1d: Communication of HPV Data Evaluation Results

Question 1d. In communicating HPV Challenge information to interested parties, what specific information elements (e.g., raw data, technical reports, fact sheets, industry summaries, EPA summaries) should be conveyed and in what form (e.g., internet, hard copy, etc.)? How would this need change as non-SIDS endpoints (including any available exposure information) become available?

OPPT has a commitment under the auspices of the HPV Challenge Program to ensure transparency of and public access to HPV data. In addition to making the technical information publicly available, EPA recognizes that for some audiences additional ways of communicating the data must be considered. As steps are taken to evaluate the HPV hazard data, and any related exposure and use information, the results of such evaluations should also be made publicly available. OPPT realizes that there are many potential audiences for such information beyond technical audiences, and that each of these have their own needs (e.g., workers, general public, etc.). There are two main topics of interest: the appropriate communication venue and the appropriate content/substance of the communication.

The Internet is an excellent tool for communicating large amounts of data. Yet, not everyone has easy access to the Internet or may know how to search it effectively. Communication through other media (e.g., brochures, reports, newspaper, broadcast) may be needed. Use of local partners may help target selected information to specific local needs.

The robust summaries currently on EPA website serve the purpose of providing hazard information to a technical audience. There are three issues associated with making this information available to a wider, public audience: (1) making the hazard information meaningful to the lay public; (2) interpretation of the hazard data *per se* and in conjunction with exposure information/scenarios to provide an assessment of potential risks; and (3) how best to communicate pollution prevention and risk mitigation options. EPA is seeking the advice of the NPPTAC in all of these areas.

Question 1e: Evaluation of the Category Approach in the HPV Challenge Program

Question 1e. What have all parties learned from applying the category approach thus far and are there approaches that could improve application of categories in the HPV program?

A key feature of the HPV Program is the use of categories, where scientifically justified, in generating and making publicly available a minimum hazard data set for the sponsored HPV chemicals. A chemical category, for the purposes of the HPV Program, is a group of chemicals whose physicochemical and toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. These structural similarities may create a predictable pattern in any or all of the following parameters: physicochemical properties, environmental fate

and environmental effects, and human health effects. The similarities may be based on the following:

a. a common functional group (e.g., aldehyde, epoxide, ester, etc.); or
b. the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g., the "family approach" of examining related chemicals such as acid/ester/salt); and
c. an incremental and constant change across the category (e.g., the dimethylene group difference between adjacent members of the alpha-olefins)

Categories can sometimes apply to series of chemical reaction products or chemical mixtures that are, again, related in some regular fashion. Analogous to the basic "discrete chemical" category model, in a mixture category some, but not all, of the individual mixtures may undergo testing. Categories accomplish the goal of the HPV Program to obtain screening level hazard information through the strategic application of testing some, but not all, members of a category. If these test results show that the chemicals in the category behave in a similar or predictable manner, then interpolation and/or extrapolation can be used to assess the chemicals in lieu of conducting additional screening-level testing.

For example, under the OECD HPV SIDS Program, some instances have been identified where, using chemical category approaches, less than a full set of SIDS data for every chemical in the category has been judged sufficient for screening purposes. This alternative helps to reduce burden on industry, as well as minimize animal testing concerns. Guidance on the development and implementation of categories in the HPV program is provided on the website at http://www.epa.gov/chemrtk/categuid.htm.

The category approach has been applied in the majority of the HPV submissions to date. As of October 3, 2003, 928 chemicals were submitted as part of the 96 category submissions. These 928 chemicals represent 86% of the total 1,081 chemicals that have been submitted. The number of chemicals in a given category range from 2 to as many as 161 HPV chemicals. The different approaches used by sponsors have varied widely and have shown a variety of complicating factors. For example, in some cases, public comments on a category have raised questions about the technical soundness of a category proposal. Also, some category proposals – whether they were questioned in terms of their technical soundness or not – did not propose any additional testing. In such cases, the submission is simply a proposal that the members of the category belong together, without an analysis showing how each category member should be "treated" in terms of a hazard analysis. This is important for understanding how "untested" category members should be characterized in a hazard screening exercise. The HPV Program has reached the point where most of the early category proposals have completed their proposed testing and some of the sponsors are in the process of reviewing the data to determine whether their original category hypothesis holds. OPPT has recently begun receiving these analyses.

EPA is interested in the NPPTAC's advice on use of the category approach thus far and potential approaches that could improve application of categories in the HPV program.

Question 1f: HPV Chemicals Beyond the Challenge Program

<u>Question 1f.</u> How should HPV chemicals that were not covered under the HPV Challenge (because they were inorganic or were not identified in the 1990 IUR reporting) be addressed?

The Program has provided a jump start for the collection of basic screening level hazard information on hundreds of chemicals. Additionally, this information has been made public on the EPA HPV Challenge Program website (http://www.epa.gov/chemrtk/volchall.htm).

This Program was established to include a finite group of HPV (primarily organic) chemicals identified in the 1990 IUR reporting cycle. EPA is interested in recommendations from the NPPTAC on how EPA and its partners should deal with:

a. orphan chemicals under the current HPV Challenge Program that are not sponsored; and

b. HPV chemicals that are reported in the 1994, 1998 or 2002 IUR reporting cycles, but that were not identified in the 1990 reporting cycle;

EPA is also interested in the NPPTAC's advice on if and when HPV inorganic chemicals should be addressed. In this regard, note that reporting on production for inorganic chemicals will commence in 2006 under the IURA.

Question 2:
Background Information and Issues Relating to Enhancing Chemical Risk Assessment and Risk Management in OPPT's Programs

***Question* 2** **OPPT believes it is important to assess existing chemicals and effectively identify and reduce risks for many more chemicals at a much faster pace than ever before. Given this objective, and the opportunities to evaluate existing chemicals which are presented by data and information that are being made available (examples include the HPV Challenge Program, TSCA §8(e), PFOS/PFOA, and VCCEP) :**

- **How much emphasis should be placed on regulatory action and how much on voluntary alternatives when collecting information, and assessing and managing risks of chemicals?**
- **What approaches (regulatory or voluntary) could OPPT take to ensure that risk assessments are transparent, clear, consistent and reasonable yet are completed on a timely basis?**
- **What approaches could OPPT undertake to ensure sufficient and timely risk management action?**
- **Are there ways in which EPA can more effectively use TSCA Section 6 to mitigate risk?**
- **What factors/criteria should OPPT use to determine which chemicals should be addressed and managed as chemicals of national concern requiring a high level of attention by OPPT?**
- **How should OPPT approach the risk assessment/management of newly identified chemicals of national concern? What directions could be pursued to further address the current chemicals of national concern (e.g. lead, mercury)?**
- **Under what circumstances could parties other than EPA (e.g., industry, non-governmental organizations, state agencies, Tribes, or others) play a role in developing and making publicly available risk assessments, and in participating in risk management actions? Under what circumstances could these parties provide assessment tools and models. What role should EPA play in such a context of shared stewardship (provide guidance, comments, data/information, tools and models, a common forum, etc.)?**

OPPT currently applies a mix of regulatory and non-regulatory approaches to assess and manage toxic chemicals. In some cases Congress has legislated specific actions to manage risk of particular chemicals that have posed a significant risk to public health and the environment (e.g., polychlorinated biphenyls (PCBs), asbestos, and lead). In other cases, OPPT relied upon implementing the regulatory framework under the Toxic Substances Control Act (TSCA) of

1976 for assessing and managing chemical risk. OPPT has done this by using its authority under TSCA §§ 4 and 8 to require the hazard and exposure information necessary to assess and potentially manage risk. More recently, OPPT has increasingly relied upon voluntary action by the regulated community as a complementary approach to the regulatory scheme.

Obtaining Relevant Information for Risk Assessment Purposes

EPA defines risk assessment as the process used to evaluate the degree and probability of harm to human health and the environment from such stressors as pollution or habitat loss. The risk assessment process the Agency follows is based on a proposal by the National Academy of Sciences and consists of:

- Exposure Assessment - describing the populations or ecosystems exposed to stressors and the magnitude, duration, and spatial extent of exposure
- Hazard Identification - identifying adverse effects (e.g. short-term illness, cancer) that may occur from exposure to environmental stressors.
- Dose-Response Assessment - determining the toxicity or potency of stressors
- Risk Characterization - using the data collected in the first three steps to estimate and describe the effects of human or ecological exposure to stressors.

There are relatively few chemicals in commerce for which extensive and sufficient data exist for evaluating potential health or environmental hazards, or exposures for risk assessment purposes. TSCA provides several regulatory tools for EPA to obtain needed data. Under TSCA §4, EPA can require the development of data via rulemaking or through an Enforceable Consent Agreement (ECA), or receive reporting by industry via TSCA §8 (i.e., inventory information through §8(a) and substantial risk information through §8(e)).

In order to issue a test rule under TSCA §4, EPA must make certain statutory findings about the substance involved.[10] Rulemaking under TSCA §4 has generally been both lengthy and resource-intensive. As a result, data have been generated under TSCA §4 test rules on only approximately 140 chemicals since the 1970s. An ECA is a publicly negotiated agreement between EPA and interested parties that requires the generation and submission of data to EPA. ECAs are usually less resource-intensive than test rules and can be a much quicker way to obtain data. Since October 1984, EPA has issued a number of ECAs covering approximately 60 chemicals.

An example of a current ECA under development is the effort to obtain additional information for PFOA (perfluorooctanoic acid and its salts), a synthetic chemical used as an essential processing aid in the manufacture of fluoropolymers in many industry segments. In response to emerging concerns, industry has voluntarily helped assemble and submit initial data on exposure, facilitating the preparation of EPA's preliminary risk assessment, which was

[10] The statutory findings include that there are insufficient data available to determine the effects of the substance on health and/or the environment; and testing is necessary to provide such data; and the substance may present an unreasonable risk of injury to health or the environment," (known as the "risk-based finding"); and/or may be produced at substantial quantities and is reasonably expected to enter the environment in substantial quantities; or may result in significant or substantial human exposure (known as the "exposure-based finding").

released in April 2003. EPA has also identified areas where additional information could be helpful in allowing the Agency to develop a more accurate assessment of the potential risks posed by PFOA, and is currently requesting additional data and public comment on its preliminary scientific findings.

The rulemaking authority under TSCA §8 provides EPA with a mechanism to obtain certain exposure data from manufacturers and processors of HPV chemicals. As a result of a recent Inventory Update Rule Amendments (IURA) (68 FR Number 4, January 7, 2003, pp. 848-906), beginning with the 2006 reporting year, initial screening level exposure-related data about uses, number of processing and use sites, and workers exposed to HPV chemicals will be reported to EPA/OPPT. A previous voluntary effort called the Use and Exposure Information Project (UEIP) demonstrated that useful screening level exposure information is available from industry and can be used to prepare screening level exposure assessments. The UEIP was a cooperative effort begun in the fall of 1992 between government and industry in recognition of the difficulties encountered in obtaining accurate and up-to-date exposure information on HPV chemicals. Data collected by EPA under the UEIP were similar to those now being required under IURA. In contrast to the IURA, however, the UEIP only provided onetime reporting of information by a subset of the manufacturers of a small number of selected HPV chemicals (68 FR Number 4, January 7, 2003, p. 853).

As a complement to the regulatory actions used to obtain data and assess risk, OPPT has increasingly relied upon voluntary action by the regulated community as an alternative way of obtaining information. OPPT's most extensive efforts to obtain screening data are being conducted under several voluntary programs that will provide an abundance of hazard data on a relatively large number of chemicals. The High Production Volume (HPV) Challenge Program and the Voluntary Children's Chemical Evaluation Program (VCCEP) have enabled EPA to obtain needed data on existing chemicals on a scale not previously seen. Through the HPV Challenge Program, industry has volunteered to publicly provide screening-level hazard data on over 2,100 high production volume chemicals (i.e., those chemicals produced in quantities of one million pounds or more per year) through 2005, and in VCCEP, to provide data on 20 chemicals thought to be of particular concern to children.

Risk Management Activities at OPPT

EPA's most extensive chemical risk management actions under TSCA have been taken in cases where Congress specified in the legislation comprehensive risk assessments and/or mitigation for chemicals that have presented serious concerns of a national scope (e.g. PCBs, lead, asbestos). These legislated chemicals are part of a small set of chemicals of national concern (national program chemicals) where OPPT has undertaken longer-term comprehensive efforts to manage risk. These national program chemicals are ubiquitous, environmentally persistent, and toxic. Other chemicals of national concern (but without the clear legislative drivers associated with PCBs, lead, and asbestos) include mercury and dioxin. In most cases, risk assessments have been completed or are in their final stages for these chemicals. The national program chemicals provide examples of where OPPT's efforts are extensively focused on risk management activities, ranging from efforts that have nearly completed their legislated

mandates (e.g., lead), to ones that are the subject of legislative proposals and other emerging mandates (e.g., mercury).

TSCA §6 provides EPA with authority to regulate the manufacture (including import), processing, distribution in commerce, use, and disposal of chemical substances and mixtures that "present or will present an unreasonable risk of injury to health or the environment." EPA and the courts have interpreted the "unreasonable risk" standard to involve a consideration of the risks posed to health or the environment by a particular activity involving a chemical or mixture as compared to the benefits associated with such activity, along with a consideration of the availability of substitutes. Under TSCA §6 authority, EPA may ban the manufacture or distribution in commerce, limit use, require labeling, or place other restrictions on chemicals that pose unreasonable risks – after making the necessary statutory findings. TSCA §6 directs EPA to select requirements necessary to protect adequately against the identified risk using the least burdensome requirements. Therefore, in promulgating regulations under TSCA §6, EPA must consider:

- The effects of the chemical substance on health and the magnitude of human exposure.
- The effects of the chemical substance on the environment and the magnitude of environmental exposure.
- The benefits of the chemical substance and the availability of substitutes.
- The economic consequences of the rule.

TSCA §6©) and §9[11] also require EPA to consider whether other Federal statutes and regulations are available to address a risk that would otherwise merit regulatory action under TSCA Section §6(a)[12].

EPA has regulated a number of substances under TSCA §6 via proposed and final rulemaking procedures: metalworking fluids (40 CFR part 747) and hexavalent chromium chemicals (40 CFR part 749). In addition, polychlorinated biphenyls (PCBs) (40 CFR part 761), and asbestos (40 CFR part 763) risk management actions have also been promulgated under TSCA §6; however, in both cases statutory requirements were followed (TSCA §6(e) and TSCA §203 [part of Title II of TSCA], respectively). Table 1 provides a summary of the actions proposed and/or finalized pursuant to TSCA §6 authority

Some EPA TSCA §6 proposals have either been remanded (asbestos) or withdrawn (acrylamide). In 1989, the Asbestos Ban and Phase-Out Rule (ABPO) under TSCA §6 banned asbestos and asbestos-containing products, such as pipeline wraps, vinyl tiles, and disc break

[11] TSCA §9 addresses EPA's authority to regulate chemical substances and associated activities that fall under both TSCA and other federal laws. It includes procedures under which EPA can refer the regulation of chemicals to other agencies and requirements to coordinate actions taken under activities with other federal agencies "for the purpose of achieving maximum enforcement of this act [TSCA] while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes".

[12] TSCA §6(a) gives EPA the authority to regulate the manufacture (including import), processing, use, distribution in commerce, and disposal of chemical substances and mixtures that present or will present an unreasonable risk to human health and the environment.

Table 1. Proposed or Final Control Actions Using TSCA Section 6 Authority

Action	Proposal Date	Final Date	Prompting Action	Present Status
Ban on manufacture, processing, distribution in commerce of fully halogenated chlorofluoralkanes for aerosol propellents	5/13/77	3/17/78	Component of federal actions regarding ozone-depleting CFCs	Superceded by later air regulations
Ban on manufacturing, processing, distribution in commerce and use of PCBs	6/7/78	5/31/79	Implemented statutory ban on PCBs	Ban in place -- numerous other actions taken to regulate certain PCBs uses
Ban on storage and disposal of dioxin-contaminated waste at one facility in Arkansas	3/11/80	5/19/80	Imminent Hazard (withdrawn in light of RCRA authority)	Superceded by 1984 RCRA rule.
Limited certain uses of metalworking fluids (3 separate actions)		½3/84 6/14/84 9/20/84	Unreasonable risk of injury to human health	Bans presently in place
Ban on manufacture, importation, processing, and distribution of asbestos	½9/86[1]	7/12/89	Unreasonable risk of injury to human health	Ban on existing uses overturned ("Corrosion Proof Fittings" case) in court in 1991; Ban on new uses remains in effect
Ban on hexavalent chromium chemicals in comfort cooling towers	3/29/88	1/30/90	Final EPA health assessment for chromium and subsequent listing as a hazardous air pollutant	Ban presently in place
Regulation of "Land Application of Sludge from Pulp and Paper Mills Using Chlorine and Chlorine Derivative Bleaching Processes"	5/10/91		Unreasonable risks to wildlife and humans presented by dioxins and furans in certain paper mill sludges	MOAs[2] entered into with pulp and paper industry; Water rule promulgated
Ban on acrylamide/–methylacrylamide grouts	10/2/91		Worker exposure issue – known human neurotoxicant, probable human carcinogen	Proposal withdrawn (12/2/2002) based on development of PPE[3]
Ban on lead fishing sinkers	3/9/94		Response to Citizen's Petition	Final action under development

1 Advanced notice of proposed rulemaking (ANPR) issued on 10/17/79.
2 MOAs = Memoranda of Understanding.
3 PPE = personal protective equipment. It was determined that the newly developed PPE provided adequate protection from exposure to acrylamide.

pads (54 FR 29460, July 12, 1989). In 1991, the United States Court of Appeals for the Fifth Circuit Court overturned much of the ABPO. Today, only a few items remain on the list as banned products, including roofing felt, millboard, rollboard; commercial, corrugated, specialty paper, and any new uses for asbestos (regulated under TSCA); spray-applied asbestos-containing materials and wet-applied or pre-applied asbestos pipe insulation (regulated under CAA) (58 FR 58964, November 5, 1993 and 59 FR 33208, June 28, 1994).

In the acrylamide case, EPA proposed a rule to prohibit the manufacture, distribution in commerce, and use of acrylamide grout (56 FR 49863, October 2, 1991) in order to protect grouters from alleged neurotoxic and carcinogenic risks arising from significant dermal and inhalation exposure to the acrylamide and N-methylolacrylamide (NMA) in these grouts. The proposal was withdrawn 11 years later based on the development of affordable personal protective equipment that could provide adequate protection from exposure to the acrylamide and NMA in these grouts (67 FR 71524, December 2, 2002).

Another regulatory risk management tool used for chemicals is TSCA §5(a)(2) - Significant New Use Rules (SNURs). Under TSCA §5(a)(2), EPA is authorized to designate a use of a chemical as a significant new use, based on consideration of several factors, including the anticipated extent and type of exposure to humans and the environment. A SNUR requires that manufacturers, importers, and processors of such substances notify EPA at least 90 days before beginning any activity (via a Significant New Use Notification, or SNUN) that EPA has designated as a "significant new use" (40 CFR 721). OPPT reviews the SNUN to determine whether it is necessary or appropriate to further regulate the substance under TSCA §§ 5(e) or 6, for example, before the new use begins.

The perfluoralkyl sulfonates (PFAS) SNUR is a recent example of an existing chemical SNUR (proposed FR 65 62319, October 18, 2000; supplemented 67 FR 11014, March 11, 2002; and finalized 67 FR 72854, December 9, 2002). Seventy-five substances are identified in the rule, and the intended manufacture or import of any of them for any use not identified in the rule would trigger the SNUR reporting requirements.

EPA is requesting advice from the NPPTAC on how to identify and implement the best "mix" of regulatory and voluntary options to achieve sufficient and timely risk assessments and risk management actions for existing chemicals in U.S. commerce, and what opportunities exists for partnership with industry, non-governmental organizations, States, Tribes, and others.

Question 3:
Background Information and Issues Relating to Enhancing OPPT's New Chemicals Program

Question 3 . Based on domestic and international experience and approaches, how can the U.S. enhance its new chemicals assessment scheme?

- **Do the current PMN reporting requirements, in conjunction with EPA's assessment (hazard, exposure, risk), risk management, and pollution prevention approaches to new chemicals, provide an adequate and informed basis for preventing chemicals of significant risk to human health and the environment from entering commerce?**
- **Are there other approaches that can be taken in the New Chemicals Program to further enhance efficiency and effectiveness of the program, and improve awareness of potential impacts of chemicals early on?**
- **Given the globalization of the chemical industry, are there approaches being used in other countries that may have value in the US scheme?**

EPA's New Chemicals Program

Under the Toxic Substances Control Act (TSCA), all chemicals in U.S. commerce are required to be listed on the TSCA Chemical Substances Inventory ("Inventory"). Chemicals not listed on the TSCA Inventory are considered new chemicals, and notification must be provided to EPA before they are manufactured or imported for commercial purposes. Certain genetically modified microorganisms are also considered new chemicals. EPA's New Chemicals Program was established to help manage the potential risk from chemicals new to the marketplace. The New Chemicals Program reviews new chemicals notification and assesses the need for and, if necessary, sets restrictions on the manufacture or use of new chemicals before they enter commerce.

To review the new chemical notifications OPPT has developed the TSCA §5 Premanufacture Notification (PMN) Review Process. Manufacturers (which includes importers) of new chemicals must give EPA a 90-day advance notification of their intent to manufacture a new chemical by filing a PMN application.[13]

The PMN review process consists of four successive technical phases, structured to quickly assess and "drop" substances of low-risk from review and to assess in more detail those substances of potential greater risk. These phases include the: chemistry review, hazard

[13] There are exemptions to the 90-day review period including the low volume exemption (LVE), the polymer exemption, the test marketing exemption (TME), and the low releases/low exposures (LoRex) exemption.

(toxicity) review, exposure evaluation, and risk assessment/risk management review. If within the 90-day review period the Agency does not take regulatory action on the new chemical, then the company may begin manufacture and must file a Notice of Commencement (NOC) form within 30-days of initial manufacture. Following receipt of the NOC, the chemical substance is added to the Inventory. Almost 90 percent of PMNs submitted to EPA complete the review process without being restricted or regulated. However, if it is determined that the substance or its use may or will pose an unreasonable risk, EPA has authority to limit or ban the substance through regulation and/or to require the development of information needed to adequately assess the risk.

The PMN Review Process is designed to accommodate the large number of PMNs received (over 1,500 annually), to assess the risks posed by each substance adequately within the strict timeframe prescribed by TSCA, and to maximize the efficiency of staff resources. The information required on the PMN application is: company name; chemical identity; production volume; intended use; manufacture, process and use information; and worker exposure and environmental release information. Although TSCA does not require that the submitter conduct laboratory tests to evaluate potential hazards of the chemicals, PMN submissions must include any existing human health/environmental effects data in the possession of the submitter, parent company, or affiliates.

EPA has developed and relies on Structure Activity Relationship (SAR) analysis to assess physical/chemical properties, environmental fate, and human and environmental effects of new chemicals, based on their structural similarity to chemicals for which data are available. A SAR is the relationship between the chemical structure of a molecule and its properties, including any possible interaction with the environment or organisms. The PMN process is largely reliant on SAR analysis since 67% of PMNs include no test data, and 85% include no health data (EPA, 2003. Presentation on the PMN Structure Activity Team http://www.epa.gov/oppt/newchems/denver/). EPA's New Chemicals Program has established 55 chemical categories to facilitate the PMN review/regulatory process (http://www.epa.gov/oppt/newchems/chemcat.htm). EPA is continuing to refine the boundaries and definitions of such categories.

If it is determined during the PMN review that a new substance presents or will present an unreasonable risk, EPA has authority to limit or ban it through regulation under TSCA §6. EPA may also limit or ban a new chemical substance under a TSCA §5(e) (Consent) Order pending development of information needed to adequately assess the risks if EPA determines that (1) insufficient information exists to permit a reasoned evaluation of the health and environmental effects of a chemical substance, and (2) the chemical substance may present an unreasonable risk to health or the environment, or it will be produced in substantial quantities and may either enter the environment in substantial quantities or lead to significant or substantial

human exposure.[14] Thus, TSCA §5(e) offers effective and flexible regulatory tools to obtain needed information, manage risk, and accomplish P2 objectives relative to new chemicals.

Another regulatory risk management tool applicable to new chemicals is TSCA §5(a)(2) - Significant New Use Rules (SNURs). Under TSCA §5(a)(2), EPA is authorized to designate a use of a new chemical as significant new use, based on consideration of several factors, including the anticipated extent and type of exposure to humans and the environment. EPA generally promulgates a "new chemical SNUR" under TSCA §5(a)(2) on a given chemical to mimic any §5(e) Consent Order applicable to the PMN submitter of the chemical to bind all other manufacturers and processors of the former new chemical to the terms and conditions contained in the Consent Order. The SNUR requires that manufacturers, importers, and processors of such substances notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use" (40 CFR 721). Such a SNUR would require the submission of a Significant New Use Notification (SNUN) 90 days prior to commercial manufacture not conforming to the conditions of the SNUR.

OPPT has taken regulatory actions (or obtained voluntary testing commitments) on approximately 3,536 (~10% of the total PMNs submitted) PMNs from 1979 - September 30, 2002. Included in this number were PMNs withdrawn voluntarily by the submitter (almost half - 1,552), often in the face of potential action by EPA.

The success of OPPT's New Chemicals Program was recently recognized by the U.S. Office of Management and Budget (OMB) which rated the program the highest of eleven EPA programs evaluated (http://www.whitehouse.gov/omb/budget/fy2004/pma.html).

Although the New Chemicals program does not require the submission of hazard data up front, companies are encouraged to assess the potential hazard/risk associated with new chemicals voluntarily. For example, through the Sustainable Futures Initiative (67 FR 76282-76292, December 11, 2002) voluntary pilot project, companies are encouraged to voluntarily use tools such as the Pollution Prevention (P2) Framework[15] to assess potential hazard/risk of new chemicals prior to submitting a PMN. The goal of this pilot project is to encourage the application of P2 principles during the development of new chemicals submitted as PMNs and the development of inherently low hazard chemicals. Furthermore, OPPT seeks to gain

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[14] OPPT's new chemicals program criteria for exposure-based policy testing were announced to the chemical industry in 1988 (see www.epa.gov/opptintr/newchems/expbased.htm). The policy defines produced in substantial quantities as substantial production (100,000 kg/yr) AND substantial or significant human exposure (various combinations of numbers of workers and levels of exposure in mg/day by exposure route; or presence in consumer product where exposures are likely; or exposure to the ambient general population at levels greater than or equal to 0.003 mg/kg/day via drinking water, air, or groundwater; or greater than or equal to 10,000 kg/year release to environmental media) OR substantial release to the environment (greater than or equal to 1,000 kg/year total release to surface water calculated after wastewater treatment).

[15] The P2 Framework is an approach to using screening-level models to screen new chemicals for development. One of those tools is the PBT Profiler, which is a screening tool to estimate persistence, bioaccumulation potential, and toxicity.

additional data and experience regarding the P2 and risk reduction benefits of the use of hazard, exposure, and risk screening methodologies in new product development efforts.

Approaches to New Chemicals in Other Countries

There are various approaches to addressing new chemicals across the globe. Because chemicals in commerce are an international business, knowledge of other non-U.S. regulatory approaches may be informative regarding the U.S. New Chemicals Program. New chemicals programs may differ in the point at which a notification is required (premanufacture or premarketing), in terms of data required to be submitted with the new chemical application, and approaches to hazard and risk assessment during the new chemical review process. For instance, in contrast to the U.S. (which requires manufacturers to submit chemical test data only if it is already available), countries such as Australia, Canada, Switzerland, the European Union, and Japan all have requirements for submission of certain types of data at the time of notification. The type of data required in these countries often depends on factors such as the quantity of the substance produced and the projected risk/exposure. For example, in addition to basic toxicity/ecotoxicity and human health data, Australia requires test data on biodegradability and bioaccumulation for a standard notification. However, biodegradability/bioaccumulation data is not required in Australia for notifications on chemicals of lesser concern, such as low volume chemicals. Japan requires a biodegradability test, and in the case of low biodegradability, subsequent testing for bioaccumulation, and mutagenicity. New Zealand requires information on disposal, uses through the substance's life cycle, and inclusion of any evaluations from other countries. Canada allows data to be supplied as test data or surrogate data (i.e., non-test, calculated data). Another example of differences in handling new chemicals across the globe is regarding the hazard/risk assessment process. For example, in Japan, all chemicals are classified by a government hazard and risk assessment committee as to whether they are mutagens (strong, weak, or negative). In Switzerland, a new chemical manufacturer is required to conduct an environmental hazard and risk assessment and submit an environmental impact report to the government for hazard and risk review. The European Union (EU) currently requires a "base set" test package that is considered a minimum premarketing data set (MPD). The MPD includes physicochemical properties, environmental fate (biodegradation) information, ecotoxicity (acute aquatic toxicity in fish and invertebrates), and health effects data (acute, repeated dose and genotoxicity studies) (Directive 79/831/EEC).

As a result of the globalization of the chemical industry, many companies are faced with the increasing challenges and costs of compliance with many different laws and regulations for new chemicals that vary among countries.[16] At the same time, resources available to authorities have, in many cases, remained static or been diverted to other areas relating to chemicals. Thus, organizations such as the Organization for Economic Co-operation and Development (OECD) have recognized a need for – and value in – better aligning new chemicals systems in the global market (e.g., to reduce economic burdens for industry, facilitate exchange of information and assessments among governments, and reconcile inconsistencies). The OECD recently

[16] McBain, D. and J.A. Hewitt. "Mutual Acceptance of Notifications – Recent Developments and Outlook." Presentation at the ChemCon 2002 International Conference on Chemical Control Regulations, June 3rd to 7th, 2002, Basel, Switzerland.

established a New Chemicals Task Force with the objective of working towards increased cooperation and efficiency of new chemical notification and assessment systems in the global market. The Task Force is engaging in activities such as the development of a standard notification form to simplify reporting and facilitate data sharing, a standard format for assessment of new chemicals, and harmonized exclusions and standard exemptions. Although the various country requirements for protecting Confidential Business Information (CBI) is a significant challenge to overcome, the Task Force has made some progress. Another important goal of the Task Force is to develop a system for using notification and assessment information on a new industrial chemical in one OECD country to facilitate the process in other countries (e.g., notified once, accepted everywhere) through a Mutual Acceptance of Notifications (MAN) process. Although consensus on the concept of MAN has not yet been reached internationally, the OECD continues to work on advancing understanding and implementing terms of the MAN concept.

EPA is interested in advice from the NPPTAC on how the U.S. can enhance its new chemicals assessment scheme.

Question 4:
Background Information and Issues Relating to Pollution Prevention in Chemicals Management

Question 4. What are the avenues for increasing the use of pollution prevention (P2) solutions in managing risks of chemicals? For example:

- **What practical steps and implementation strategies could be pursued in the TSCA program that would contribute to preventing pollution and/or potential risk from chemicals?**
- **How could OPPT's existing tools and approaches (e.g., P2 Framework, TSCA §§5(a)(2) and 5(e)) be further integrated to prevent pollution and manage the risk of chemicals more broadly?**
- **What are opportunities to broaden pollution prevention solutions in the realm of existing chemicals? Do barriers exist to broadening pollution prevention in OPPT's new and existing chemicals programs, and, if so, how could they be broken down?**
- **What incentives (economic or others) can be created to encourage prevention as a key mechanism for managing risks of chemicals?**
- **What should be the pollution prevention components in a successful product stewardship program?**

In the mid to late 1970s, EPA focused on the control of current sources of pollution using "end-of-pipe command and control" approaches. Over the next two decades, the approach to environmental protection evolved to include a stronger emphasis on prevention of pollution, or "source reduction". Although pollution prevention (P2) at EPA in the 1980s was largely limited to TSCA new chemicals review, waste minimization activities and a few facility-specific projects, P2 gained additional momentum in 1990 with the implementation of a series of EPA prevention-focused programs and the passage of the Pollution Prevention Act (PPA). In the mid-1990s, the Agency committed to incorporating formalized prevention practices into its mainstream activities through regulations, permitting, technical assistance, and enforcement. The Agency established P2 objectives for partnerships, public information policies, technological innovation, and regulations, as well as encouraged other government agencies to continually renew their commitment to P2 efforts.

In managing EPA's chemicals program, OPPT has actively sought opportunities to promote P2 and pollution reduction in managing risks of chemicals. OPPT promotes regulatory and voluntary efforts for the design, development, and application of safer chemical processes and technologies. OPPT's efforts have included, for example, consideration of P2 opportunities

when assessing new chemical applications, P2 information (when available) and options when performing assessments of existing chemicals, and technical support for P2 via grants to States.

OPPT's voluntary P2 tools and approaches include:

- Sustainable Futures: a pilot project designed to encourage the application of P2 principles during the development of new chemicals submitted as Premanufacture Notifications (PMNs) under TSCA §5.
- Pollution Prevention (P2) Framework: a compilation of models that OPPT developed. To support the Sustainable Futures pilot program, OPPT is using the P2 Framework to predict risk-related properties of chemicals using structure activity relationships (SARs) and standard (default) scenarios. The P2 Framework combines several of OPPT's models to estimate physical and chemical properties and environmental fate (EPI SUITE), models to estimate hazards to humans and the environment (OncoLogic, ECOSAR, PBT Profiler), and models to estimate exposure and/or risk (E-FAST and ChemSTEER). The P2 Framework Project presents these models to industry with the hope that the models will be useful in identifying potential problem chemicals and processes early in the research and development (R&D) process.
- Design for the Environment (DfE): a voluntary partnership program that helps businesses design or redesign products, processes, and management systems that are cleaner, more cost-effective, and safer for workers and the public; projects look at cross-media impacts, energy and resource use, and the potential risks from chemicals.

- Green Chemistry Program: an initiative under EPA's DfE Program that focuses on P2 through the environmentally conscious design of chemical products and processes.
- Green Engineering: an initiative under the DfE program designed to promote the development and commercialization of environmentally beneficial design methods, risk-based design tools, and green technologies via education, outreach, and partnering with the academic, research, and industrial communities.
- Environmentally Preferable Purchasing (EPP): a federal government-wide program managed by EPA that assists Executive agencies in the purchasing of environmentally preferable products and services.
- Green Suppliers Network (GSN): a collaborative venture between industry and EPA that works with all levels of the manufacturing supply chain; links manufacturing and technical assistance resources; emphasizes environmental and economic benefits through improved performance, minimization of waste, and removal of institutional roadblocks.
- Hospitals for a Healthy Environment (H2E): a voluntary partnership between EPA, the American Hospital Association (AHA), and its members, to implement P2 practices in hospitals.

P2 has primarily been achieved through voluntary and assistance programs, such as the ones described above. Some innovative techniques have been used to merge the voluntary and regulatory approaches by directly or indirectly promoting pollution prevention as a means for organizations to reduce their regulatory burden. One example is the use of measurement and public reporting as an incentive for P2 efforts. The Toxics Release Inventory (TRI) Program, formerly in OPPT and currently implemented through the Office of Environmental Information

(OEI) – a regulatory chemical release reporting program – also achieved voluntary pollution prevention benefits. The public reporting and notification of chemical releases under the TRI Program has enabled public pressure to serve as a strong incentive for companies to reduce the releases of TRI chemicals they manufacture or use. Local government agencies have also used TRI to set priorities, measure pollution prevention progress, and target areas of special and immediate concern for source reduction efforts.

Other innovative approaches include EPA's support for green alternatives for chemical use and production, multimedia approaches for the management of certain chemicals of concern, and full or limited life-cycle assessments and approaches. There have also been initiatives to reduce regulatory burden on organizations adopting environmental management systems and those that reduce their chemical use through pollution prevention.

The concept of pollution prevention is also a key element in the development and implementation of product stewardship programs. Product stewardship is a product-centered approach to environmental protection, that uses a life-cycle perspective to identify strategic opportunities for risk reduction, pollution prevention and resource conservation. Product stewardship calls on those involved in the product life cycle – manufacturers, retailers, users, and disposers – to share responsibility for reducing the environmental impacts of products. Product stewardship can act as a catalyst for environmental improvements by providing incentives to manufacturers to consider and take responsibility for the entire life-cycle impacts of a product. Although some regulatory policies have been put in place in the U.S. for specific products or waste streams, to date the implementation of domestic product stewardship policies has overwhelmingly been a voluntary effort. Countries within the European Union have taken a more regulatory approach through product-oriented legislation, such as mandatory take-back programs that require certain manufacturers (e.g., the automotive and electronics industries) to take back their products at the end of their life and recycle or properly dispose of them.

In addition to voluntary approaches to P2, OPPT has certain regulatory tools available that can also help to achieve P2 objectives. For example, chemicals new to the marketplace are reviewed by OPPT before they are produced or imported through the Premanufacture Notification (PMN) review process. As part of that review, P2 solutions that reduce risk may be identified. In this instance, EPA can use its authority under TSCA §5(e) and control new chemical risks via implementation of P2-based requirements.[17] There may also be opportunities for creative use of §5(a)(2) (SNURs) or other TSCA provisions to advance P2 objectives on existing chemicals.

As OPPT moves forward, these and other P2 approaches may present opportunities for broader application and further integration in OPPT's direction of chemicals management programs. EPA is seeking advice from the NPPTAC on ways to increase the use of pollution prevention (P2) solutions in managing risks of chemicals.

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[17] If it is determined during the PMN review that a new substance may or will pose an unreasonable risk, EPA has authority to limit or ban it through regulation. This includes the issuance of a TSCA §5(e) Consent Order to prohibit or limit activities associated with the new chemical, where EPA determines that insufficient information exists to evaluate the human health and environmental effects of the substance, and that it may present an unreasonable risk or be produced in substantial quantities.

Question 5:
Background Information and Issues Relating to Enhancing Partnerships with States and Tribes in Implementing OPPT's Programs

Question 5. Are there opportunities for States and Tribes to assume a greater partnership role in furthering the goals of the national program? If so, what role(s) would be optimal? Are there ways to better share chemical data with the States and Tribes while continuing to safeguard TSCA confidential business information (CBI)?

OPPT manages an extensive and varied national program for identifying and controlling chemical hazards and risks to human health and the environment. The Toxic Substances Control Act (TSCA) provides the legislative basis for this program. However, unlike other major national environmental legislation (such as the Clean Air Act), TSCA, with the exception of its programs for lead and asbestos, does not define a specific role for States and Tribes.

TSCA §10(g) authorizes EPA to coordinate a system for exchanging and standardizing chemical research results among Federal, State and local authorities. TSCA §14 limits the access that the general public, including States and Tribes, may have to certain chemical information claimed as confidential. Under TSCA §14(a) and EPA's Regulations on the Confidentiality of Business Information (CBI), EPA is prohibited from disclosing trade secrets, or commercial or financial information that is privileged or confidential, to the public, except in certain extremely limited circumstances (such as where necessary to protect against an unreasonable risk of injury to health or the environment).

Effective implementation of OPPT's programs, especially those directed at existing chemicals, can greatly benefit from the involvement of States, Tribes, and communities. Historically, partnership arrangements between EPA and States/Tribes have proven to be beneficial in protecting the environment and providing better coordination of regulatory and voluntary efforts. For example, there is a history of significant interaction between States/Tribes and OPPT regarding voluntary efforts for pollution prevention (P2) such as the Forum on State and Tribal Toxics Action (FOSTTA) and the P2 Grants Programs managed by OPPT. OPPT is interested in other ways to improve coordination between its statutory program and the States/Tribes.

Existing Coordination Efforts with States and Tribes

EPA Regional Offices play a pivotal role in communication between OPPT and the States, Tribes, and communities. They routinely work with those entities to help them develop the technical and legal capability to facilitate the implementation of standards and regulations developed by EPA. The role of a State or Tribe in implementing a particular regulation or voluntary program can vary, but may include: compliance assistance, monitoring or incentives; education and outreach; promotion of a new strategy or initiative; and facilitation of interaction

with stakeholders. Some States have grant arrangements to perform inspections, cite violations, etc. in support of Agency efforts to enforce TSCA regulations.

Over the years, OPPT's coordination with the States and Tribes has focused on:

- TSCA requirements related to lead and asbestos,
- Voluntary programs and pilot projects, and
- Participation in partnership organizations.

Coordination on Lead and Asbestos

TSCA specifies the role States should play with regards to lead and asbestos management. For example, TSCA §404 mandates a process under which EPA will approve state programs for training and certification of lead-based paint contractors and for performing the lead education and outreach required under TSCA. EPA has promulgated a model state program that may be used by States seeking to administer training and certification programs. All state programs must be at least as protective as the Federal program and must provide adequate enforcement. In those States lacking their own programs, EPA must establish, administer, and enforce Federal programs. EPA Regions implement OPPT's lead program in States that have not accepted responsibility for the program. EPA is also authorized to make grants to States to develop and carry out the authorized programs.

Partnerships with States and Tribes

EPA Headquarters and its Regional Offices work with States and Tribes to implement many initiatives and programs. For example, to achieve the U.S. voluntary PCB decommissioning goals supported by OPPT, efforts have largely built on the Region 5 (Chicago) PCB Phasedown Program and may seek the use of cooperative agreements and consultations with States and Tribes in the future. For over 10 years, Illinois EPA (IEPA) has performed PCB inspections and prepared enforcement cases under a grant arrangement with EPA Region 5.

OPPT coordinates and partners with States and Tribes through a variety of organizations. The National Conference of State Legislators (NCSL) was founded in 1975 to provide an open, bipartisan, national forum for the lawmakers and staffs of the nation's states, its commonwealths and territories to communicate with one another and share ideas. NCSL facilitates ongoing efforts of the States and Tribes to identify, discuss, and address toxics-related issues, and to continue the dialogue on how Federal environmental programs can best be implemented. One example of a NCSL project related to OPPT efforts is the NCSL Lead Hazards Project. This project assists States on the issue of lead poisoning prevention by facilitating information exchange among the States and by promoting improved coordination between the States and OPPT.

The Forum on State and Tribal Toxics Action (FOSTTA) is a partnership between OPPT and state and tribal leaders to increase understanding and improve collaboration on toxics and P2 issues and to continue a dialogue on how federal environmental programs can best be implemented among the States and Tribes. Created in 1991, FOSTTA is currently operated

under a cooperative agreement with the Environmental Council of the States (ECOS) and the National Tribal Environmental Council (NTEC). ECOS is a national non-profit, non-partisan association of State and territorial environmental commissioners. NTEC is a membership organization dedicated to working with and assisting all federally recognized Tribes in the protection and preservation of the reservation environment. NTEC membership is open to federally recognized Tribes throughout the United States, and currently has 108 member Tribes.

ECOS, NTEC, and OPPT co-sponsor meetings of FOSTTA twice each year to examine, among themselves and with EPA officials, the nature and direction of EPA's chemical and prevention programs. FOSTTA has been moving in a new direction since 2000, building upon EPA's national HPV chemical initiative that provides an opportunity for EPA to realign and invigorate its chemical and prevention programs and to stimulate the development of new state-based capabilities in these areas. OPPT restructured its existing FOSTTA state projects into a new "Chemicals Information and Management Project" (CIMP), an existing "P2 Project", and a strengthened "Tribal Affairs Project" (TAP). CIMP focuses on EPA's toxics program and works to develop a more coordinated effort involving Federal, State, and Tribal agencies in chemical assessment and management decisions. The P2 Project promotes integrating chemical P2 into mainstream environmental activities at both the Federal level and among the States. TAP concentrates on chemical and prevention issues that are most relevant to the Tribes, including lead control and abatement, traditional/subsistence lifeways, and hazard communications and outreach.

Another point of collaboration between OPPT and the State and local governments is the National Pollution Prevention Roundtable (NPPR). The NPPR is an organization to collaborate on pollution prevention technical assistance and capacity building initiatives.

Pollution Prevention Grants

The Pollution Prevention (P2) Grant Program was created under the authority of the Pollution Prevention Act (PPA) of 1990. The program provides matching funds to States and Tribes to support pollution prevention activities. The goal is to give the State programs the capability to assist business and industry to identify better environmental strategies, identify solutions to comply with Federal and State regulations, improve business competitiveness without increasing environmental impacts. The type of projects funded under the P2 Grant Program include: technical assistance, training, outreach, education, regulatory integration, data collection, research and demonstration projects.

EPA is seeking advice from the NPPTAC on potential opportunities for States and Tribes to assume a greater partnership role in furthering the goals of the national program, as well as ways to better share chemical data with the States and Tribes while continuing to safeguard TSCA confidential business information (CBI).

Question 6:
Background Information and Issues Relating to Future Directions for OPPT's Chemical Management Programs

Question 6. What challenges and opportunities face OPPT, working in partnership with States, Tribes, industry and NGOs in managing and reducing risk associated with toxic chemicals over the next 20 years? What approaches can be taken in the interim (next 5 or 10 years) to prepare to meet those challenges successfully? How might the increased international interest and activities of governments, industry, and NGOs in global chemicals management impact domestic approaches for reducing and preventing chemical risk? What approaches should OPPT consider in planning chemicals management and prevention for the future?

The development of chemicals management in the U.S. has evolved and been shaped by various forces over the last three decades. The regulatory command-and-control approach under the Toxic Substances Control Act (TSCA) of 1976 has increasingly been complemented with voluntary and partnership approaches with industry and non-governmental organizations (NGOs). For example, the High Production Volume (HPV) Challenge Program, initiated in 1998, emphasizes partnerships with industry and NGOs and a general new approach, while still linking to and coordinating with the regulatory mandates of TSCA. U.S. producers and importers of HPV chemicals (industrial chemicals that are produced in or imported into the U.S. in volumes of 1 million pounds or more per year) voluntarily participate in the HPV Challenge Program by "sponsoring" a chemical: identifying and assessing the adequacy of existing hazard information, conducting new testing (if adequate information does not exist), and making the new and existing test results available to EPA and the public.

The initial emphasis on mitigating chemical risk has also been expanded, under the 1990 Pollution Prevention Act (PPA), to incorporate the prevention of pollution at the source and the development of new technologies and approaches. For example, in the spirit of the PPA, OPPT's Green Chemistry program was developed to encourage the design of environmentally conscious chemical products and processes; the Green Engineering program educates engineers in techniques for applying pollution prevention and risk reduction to engineering designs; and the Environmentally Preferable Purchasing program, a federal government-wide program managed by EPA, requires and assists Executive agencies in the purchasing of environmentally preferable products and services.

EPA has also worked to enhance its partnerships with States, for example, through programs such as the Forum on State and Tribal Toxics Action (FOSTTA). FOSTTA is a partnership between OPPT and state and tribal leaders to increase understanding and improve collaboration on chemicals management and P2 issues and to continue a dialogue on how federal environmental programs can best be implemented among the States and Tribes.

The advances of communications in the Information Age and the expansion of right-to-know approaches (e.g., the HPV Challenge Program) have created new audiences and increased pressure for accurate and meaningful information on managing risks of chemicals. Concerns have evolved from an initial emphasis on cancer, birth defects, and mutagenicity to encompass a wide array of issues such as developmental toxicity, reproductive toxicity, neurotoxicity, endocrine disruption, persistent bioaccumulative toxics, cumulative effects of exposures to multiple chemicals, environmental justice, and sensitive populations.

The increased importance of a global economy has also expanded the focus of chemical management from mitigating risks within U.S. borders to increasing coordination and engagement with other countries to address environmental issues collaboratively and, where appropriate, via global approaches.

An example of chemicals management in a regional context is the work of the Sound Management of Chemicals (SMOC) program under the North American Commission for Environmental Cooperation (CEC) to address environmental issues across Canada, the U.S. and Mexico. By working through the CEC's SMOC program, OPPT has assisted in the development of the North American Regional Action Plans (NARAPs) for PCBs and mercury and is currently participating in the development of a NARAPs for lead and for dioxins, furans and hexachlorobenzene.

On a more global scale, intergovernmental organizations have grown and matured to promote greater coordination and collaboration among governments, as well as global chemicals management. For example, the Organization for Economic Cooperation and Development (OECD) and the Intergovernmental Forum on Chemical Safety (IFCS) are intergovernmental groups working towards coordinating and collaborating international efforts to promote environmental, health, and chemical safety.

The OECD is an international organization consisting of representatives from 30 industrialized countries in Europe, North America, Asia and the Pacific. It has developed such programs as the Screening Information Data Set (SIDS) Program to facilitate the coordinated investigation of HPV chemicals; the Globally Harmonized System (GHS) of Classification and Labeling to promote better exchange of information on the hazards of chemicals and mixtures to human health and the environment; and the agreement among OECD countries to accept OECD Test Guideline-run studies for review regardless of where the study is performed (the Mutual Acceptance of Data, or MAD). The IFCS was established in 1994 in response to the request of governments at the United Nations Conference on Environment and Development, and reaffirmed in the 2000 Bahia Declaration, with the goal of strengthening international cooperation in improved chemical safety.

Other organizations, such as the United Nations Environmental Program (UNEP), work to promote national, and where appropriate, global efforts on chemicals. UNEP was established in 1972 under the United Nations system, and includes a chemicals unit tasked with helping governments take needed actions for the sound management of chemicals, by promoting the exchange of information on chemicals, and by helping to build the capacities of countries around the world to use chemicals safely. UNEP has supported multilateral activities such as the Rotterdam Convention on Prior Informed Consent (PIC), which prevents export of harmful

pesticides and industrial chemicals unless the importing country agrees to accept them, and the Stockholm Convention on Persistent Organic Pollutants (POPs), which is a global treaty to protect the environment from POPs. In coordination with IFCS, UNEP is developing a Strategic Approach to International Chemicals Management (SAICM), which is based on existing international commitments and takes into account economic, social, and environmental aspects of chemicals management.

At the World Summit on Sustainable Development (WSSD) held in September, 2002 in Johannesburg, South Africa, an implementation plan was adopted. The plan addresses the management of chemicals and says, in part, "....(R)enew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment, inter alia, aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment....." (see Paragraph 23 at http://www.johannesburgsummit.org/html/documents/summit_docs/131302_wssd_report_reissued.pdf).

As these, and future events continue to influence and shape chemicals management domestically and internationally through the 21st century, EPA and its partners will need to recognize and anticipate important developments in order to meet the needs of the future.

EPA is seeking advice from the NPPTAC on challenges and opportunities that face OPPT in managing and reducing risk associated with chemicals over the next 20 years, approaches that can be taken in the interim (next 5 or 10 years) to prepare to meet those challenges successfully, domestic impacts of increased international interest and activities of governments, industry, and NGOs in chemicals management, and approaches that OPPT should consider in planning for the future of its chemicals management and prevention programs.